

Notice of Allowability

Application No.

09/484,629

Examiner

Joseph T. Weitach

Applicant(s)

ROBINSON ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to April 11, 2005.
2. ☒ The allowed claim(s) is/are 8-16, 28, 31, 33-36.
3. ☒ The drawings filed on 18 January 2000 are accepted by the Examiner. *and 5/2/2001*
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on January 20, 2005 has been entered.

DETAILED ACTION

This application is an original application filed January 18, 2000, which claims benefit to foreign applications: PCT/GB99/02658, filed December 8, 1998; 9817566.4, filed August 12 1998; and 9910522.3, filed May 6, 1999, all filed in the United Kingdom.

Applicants' amendment filed April 8, 2005, has been received and entered. Claims 1-7, 1727, 29, 30 and 32 have been cancelled. Claim 28 has been amended. Claims 8-16, 28 and 31, 33-36 are pending.

Election/Restriction

As indicated previously, claim 35 is directed to a method of using a 5'OT-EST for determining mutations, polymorphisms or other changes. Claim 35 was been withdrawn from consideration as being directed to a non-elected invention (see 37 CFR 1.142(b) and MPEP 821.03). Claims 8-15, 28, 31, 33, 34 and 35 are directed to an allowable product. Pursuant to

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the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claim 35, directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, is now subject to being rejoined. Claim 35 is hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Since all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement made in the Office action mailed on February 2, 2001 is hereby withdrawn.

Claims 8-16, 28 and 31, 33, 34-36 are currently under examination.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Examiner's Amendment

Authorization for this examiner's amendment was given in a telephone interview with Barbara A Gyure on June 22, 2005.

The application has been amended as follows:

Amend claim 35 to read:

35. A method for the detection of mutations, polymorphisms or other changes in S'OT-EST which may predispose an individual to obesity, said method comprising hybridizing a nucleic acid sample from an individual to a detectable labeled probe that is capable of hybridizing to a sequence selected from the group consisting of (a) any one of SEQ ID NOs 1, 3 or 5, and (b) a

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sequence at least 90% identical over the 111 length of one of SEQ ID NOs 1, 3 or 5, [wherein] and detecting a mutation, polymorphism or other change in S'OT-EST sequence relative to SEQ ID NOs 1, 3 or 5 in said individual [is detected], wherein the mutation, polymorphism or other change in 5'OT-EST may predispose the individual to obesity.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

The TO and AVP genomic sequences have been previously described, however these cloned sequences did not contain the 5' polynucleotide sequence which comprised the 5'OT EST gene described in the instant specification. Though the prior art teaches that ESTs sharing partial homology to the 5'OT EST sequences were known, the prior art of record failed to teach the full length sequences as presently disclosed, or even to appreciate the presence of the 5'OT EST gene 13 kb upstream of the TO gene, or provide motivation to link this gene or gene product described only by the partial EST sequences with the TO gene. The OT sequences described are demonstrated to be in physical linkage to Ptpa, AVp and Oxt and provide physical markers of these genes on chromosome 2 (specification-page 9). Moreover, the use of sequences that encode a protein to make a transgenic animal demonstrate that the gene product of 5'OT EST itself is responsible for the phenotype of obesity. Briefly, it was demonstrated that over-expression of 5'OT EST and variants thereof produce a transgenic animal predisposed to obesity and complications related to this. The claims are free of the art of record because the art fails to teach or make obvious the specific SEQ ID NOs or sequences that hybridize that are 15 to 50 base pairs in length (claim 28).

Claim 35, presently rejoined with the allowed products, is directed to a method that has not been specifically examined, however in the context of the properties of the 5'OT EST has been fully considered. In light of the evidence that in human obesity is linked to alleles in chromosome 2, in particular to 5'OT EST, and the evidence provided in the transgenic animal models, there is a clear indication that 5'OT EST itself and alterations in 5'OT EST expression

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can be related to obesity. It is noted that the instant specification does not disclose any specific polymorphisms nor mutations in humans, however given level of skill in the art and the correlation of 5'OT EST with obesity, Examiner considers the method of detecting changes in 5'OT EST with a potential role in obesity fully enabled by the instant specification.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

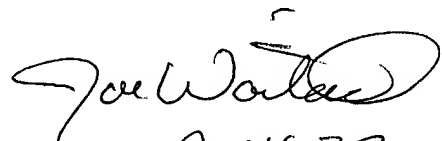
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

JOSEPH WOITACH, PH.D.
PRIMARY EXAMINER


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